K091410

510 (k) Summary of safety and effectiveness

AUG 11 2009

SUBMITTER INFORMATION

A.	Company Name:	Spes Medica s.r.l.
B.	Company Address:	Via Europa - Zona Industriale Battipaglia SA, Italy 84091
C.	Company Phone: Company Fax:	+39 0828 614191 +39 0828 341788
D.	Contact Person:	Alfredo Spadavecchia Quality Assurance Assistant Spes Medica s.r.l. E-mail: a.spadavecchia@spesmedica.com
E.	Date Summary Prepared:	May 11, 2009

DEVICE IDENTIFICATION

A.	Device name:	Disposable EMG Needle Electrodes
B.	Trade/Proprietary Name:	Disposable EMG Needle Electrodes, Myoline, Myobot
C.	Classification name:	Electrode, Needle, Diagnostic Electromyograph (21 CFR §890.1385)
D.	Product Code:	IKT

LEGALLY MARKETED DEVICES (PREDICATE DEVICES)

- MEDICOTEST A/S: Neuroline, Disposable Concentric Needle Electrodes, Neuroline, Disposable Monopolar Needle Electrodes, Diagnostic Electromyography Needle Electrode, Disposable Hypodermic Needle, K973529, K983597, K001869
- AMBU A/S: Neuroline Concentric Needle Electrode, Neuroline, Disposable Monopolar Needle Electrode, K071186, K071185
- MEDELEC: Disposable Needle Electrode, Teca Disposable Monopolar Needle Electrodes, Teca Myoject Disposable Needle Electrodes K961013, K973442, K973444
- DANTEC MEDICAL, INC.: Dantec Disposable Concentric Needle, K931966
- TECHNOMED EUROPE: Disposable Hypodermic EMG Needle Electrode K062437

DESCRIPTION OF THE DEVICE

A diagnostic electromyography needle electrode is a monopolar or bipolar needle intended to be inserted into muscle or nerve tissue to sense bioelectrical signals. The device is intended for medical purposes for use in connection with electromyography (recording the intrinsic electrical properties of skeletal muscle). The needle electrodes are for single patient only.

INTENDED USE

Recording muscle activity for Electromyography (EMG) applications. For single patient use only.

The disposable hypodermic needle is inteded to be used for injection of the Botulinum Toxin into a muscle, while recording electromyography activity. The electrode has an open lumen and is designed for muscle stimulation, motor unit action, potential recording and Botulinum Toxin injection.

Spes Medica does not supply any drugs with the needle electrodes nor does Spes Medica offer for sale any form of drugs.

SUBSTANTIAL EQUIVALENCE

The Disposable EMG Needle Electrodes and the predicate devices are similar in design, materials, packaging and other technological characteristics to the predicate devices. In further support of a substantial equivalence determination, Section 6 provides a comparison chart of the Disposable EMG Needle Electrodes and the predicate devices.

Based on the available 510(k) summaries, the marketing literature and the information provided herein, we conclude that the Disposable EMG Needle Electrodes are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Spes Medica S.r.l.
c/o Alfredo Spadavecchia
Quality Assurance Assistant
Via Europa – Zona Industriale
84091 Battipaglia (SA)
Italy

AUG 11 2009

Re: K091410
Trade/Device Name: Disposable EMG Needle Electrodes
Regulation Number: 21 CFR 890.1385
Regulation Name: Diagnostic Electromyograph Needle Electrode
Regulatory Class: II
Product Code: IKT
Dated: May 11, 2009
Received: May 13, 2009

Dear Mr. Spadavecchia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K091410

Device Name: Disposable EMG Needle Electrodes

Indications for Use:

Recording muscle activity for Electromyography (EMG) applications. For single patient use only.

The disposable hypodermic needle is inteded to be used for injection of the Botulinum Toxin into a muscle, while recording electromyography activity. The electrode has an open lumen and is designed for muscle stimulation, motor unit action, potential recording and Botulinum Toxin injection.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K091410